K071414

510(k) Summary

APR - 7 2008

1. Submitter's Name, Address and Contact Person

Submitter
Lil' Drug Store Products, Inc.
1201 Continental Place NE
Cedar Rapids, IA 52402
United States

Contact Person
Tricia Miller, Director of Quality & Regulatory
Telephone: 319-294-3745
Facsimile: 319-393-3494
Email: tmiller@lildrugstore.com

Date Summary Prepared: March 20, 2008

2. Device Information

Trade name:	Cryostat (for OTC use)
Classification name:	Device, Thermal, Hemorrhoids
Device classification:	Unclassified
Product code:	LKX
Review Panel:	Gastroenterology/Urology

3. Legally Marketed Devices to which Equivalence is Being Claimed

Device Name:	Hemor-Rite Cryotherapy
510(k) Number:	K042564
Applicant:	Fama Holdings International Corp. 6202 NW 88th Avenue Parkland, FL 33067

4. Description of Device

The Cryostat Cold Therapy Pack device consists of a combination of water and chemicals in an anatomically designed sealed plastic bag, enclosed in a cloth outer wrapper for comfort. Six Cold Therapy Packs are packaged in one carton. An individual cold pack is 95mm long and 25mm wide and 26mm in depth.

A cold pack consists of a series of inner plastic containers, one of which contains water and FDA food grade dye (to distinguish it from the other fluid), inside a second container which contains a secondary fluid, consisting of water, USP Food grade Kosher propylene glycol as well as a different color FDA food grade dye.

The freezing temperature of the first fluid is higher than that of the second fluid. This allows a time released cooling process which delivers high performance cold therapy because of conduction and convection following the phase change of the primary fluid from solid to liquid.

The containers are made of formable film common in the food and medical packaging industry. The film is a multi-layer extrusion with one layer being Nylon to add strength and act as a vapor barrier. Visual inspection is performed to verify seal integrity and the dye in the fluids facilitates quality control.

Since the intended use of the device is to treat a specific ailment which requires comfort, the miniature cold pack is then wrapped in a heat sealable fabric for comfort to the affected area. The material chosen is white, so that the device, once used can be seen as soiled and therefore is disposed of.

5. Statement of Intended Use

The device is for the treatment of external hemorrhoids by applying cold therapy (cryotherapy) directly to swollen hemorrhoidal veins. By applying the device to the tissue, the inflammation is reduced. The direct application of cold provides prompt relief of/extinguishes itching, burning, pain, and swelling. In addition, the device is beneficial for the treatment of perianal fissures due to the vasoconstriction and analgesia properties of the device.

It is intended for the over-the-counter use.

6. Statement of Technological Characteristics of the Device

Cryostat is substantially equivalent to other previously approved cold pack products with respect to its design and materials, principle of operation, function, and intended use; specifically: Hemor-Rite Cryotherapy (Fama Holdings International Corp., Parkland, FL; 510(k) number K042564).

	Cryostat	Hemor-Rite Cryotherapy
Design	ease of use, anatomical comfort	ease of use, anatomical comfort
Materials	plastic container containing liquid coolants	plastic container containing liquid coolants

Principle of Operation	cooling provided by phase transition of frozen liquid	cooling provided by phase transition of frozen liquid
Function	vasoconstriction and analgesia	vasoconstriction and analgesia
Intended Use	provide relief to body areas affected by external hemorrhoids	provide relief to body areas affected by external hemorrhoids

	Cryostat	**Cryo-Max**
Design	ease of use, anatomical comfort	ease of use, anatomical comfort
Materials	plastic container containing liquid coolants	plastic container containing liquid coolants
Principle of Operation	cooling provided by phase transition of frozen liquid	cooling provided by phase transition of frozen liquid
Function	vasoconstriction and analgesia	vasoconstriction and analgesia
Intended Use	provide relief to body areas affected by external hemorrhoids	provide relief to body areas

A rigorous risk assessment and performance test regimen demonstrated the safety and effectiveness of Cryostat. The tests performed included: temperature longevity, flammability, burst strength, tensile strength, tear strength, a safety/toxicological assessment, irritation, sensitization, and cytotoxicity.

7. Conclusion

Based on the information presented above it is concluded that Cryostat for OTC use is safe and effective for its proposed indications for treatment of external hemorrhoids and is substantially equivalent in intended use, safety, and labeling to the predicate device and the predicate device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia L. Miller
Director of Quality & Regulatory
Lil' Drug Store Products, Inc.
1201 Continental Place NE
P.O. Box 1883
CEDAR RAPIDS IA 52402

APR - 7 2008

Re: K072414
Trade/Device Name: Cryostat™
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKX
Dated: March 25, 2008
Received: March 26, 2008

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K072414

Device Name: Cryostat™

Indications for Use: The device is for the treatment of external hemorrhoids by applying cold therapy (cryotherapy) directly to swollen hemorrhoidal veins. By applying the device to the tissue, the inflammation is reduced. The direct application of cold provides prompt relief of/ extinguishes itching, burning, pain, and swelling. In addition, the device is beneficial for the treatment of perianal fissures due to the vasoconstriction and analgesia properties of the device.

Prescription Use ____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072414